DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues. The committee also advises and makes recommendations to the Secretary of Health and Human Services under 45 CFR 46.407 on research involving children as subjects that is conducted or supported by the Department of Health and Human Services (DHHS).

Date and Time: The meeting will be held on September 15, 2004, from 8 a.m. to 1 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Jan N. Johannessen, Office of the Commissioner (HF–33), Food and Drug Administration, 5600 Fishers Lane (for express delivery, rm. 17–51), Rockville, MD 20857, 301–827–6687, e-mail: *jjohannessen@fda.gov*, or FDA Advisory Information Line, 1–800–741–8138 (301–443–0572 in the

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Washington, DC area), code 8732310001. Please call the Information Line for up-to-date information on this meeting.

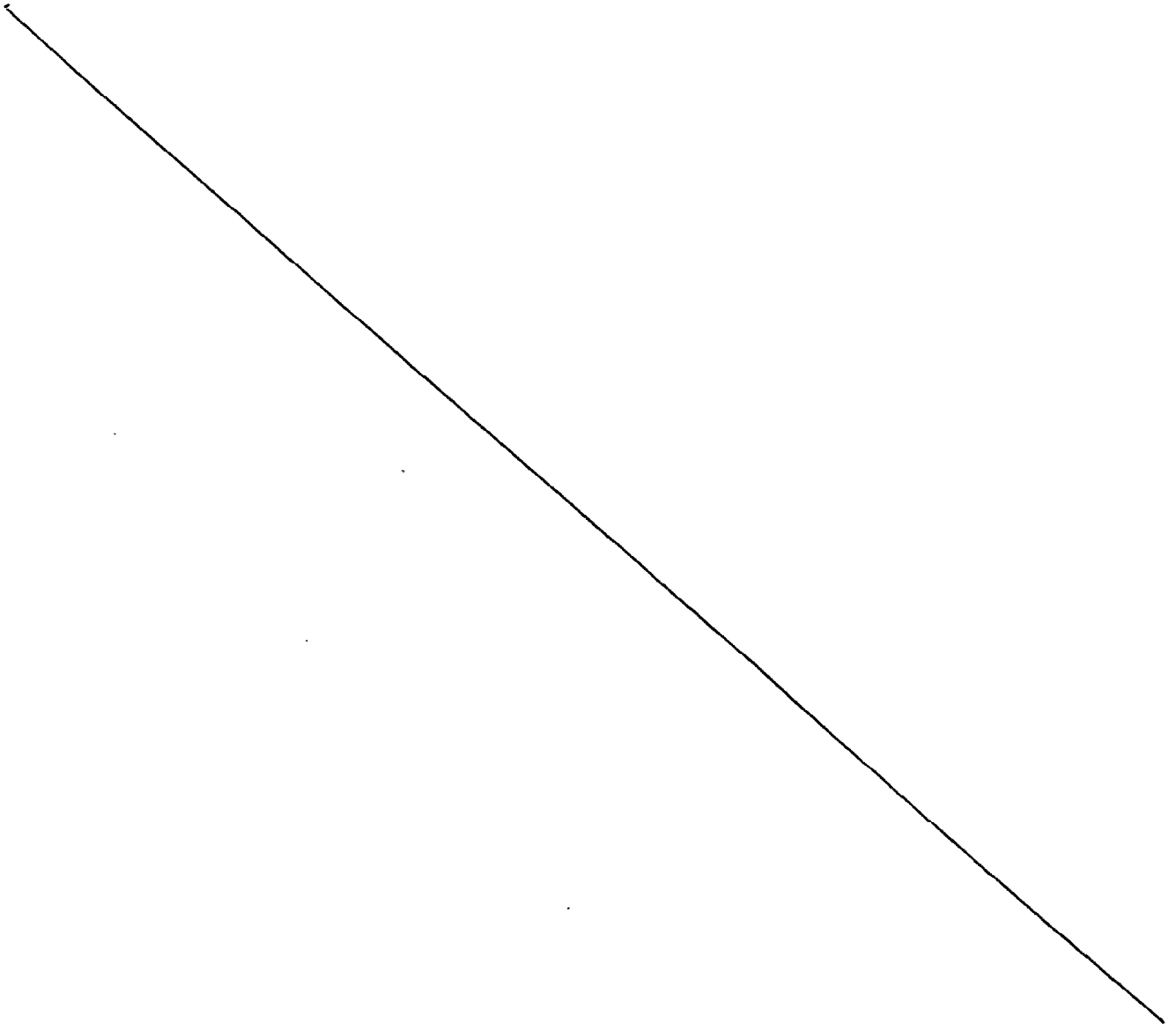
Agenda: The committee will discuss: (1) The recommendation of the Pediatric Ethics Subcommittee from its meeting on September 10, 2004, regarding a referral by an Institution Review Board under 21 CFR 50.54 and 45 CFR 46.407 of a proposed clinical investigation that involves both an FDA-regulated product and research involving children as subjects that is conducted or supported by the DHHS, and (2) a report by the agency on Adverse Event Reporting, as mandated in section 17 of the Best Pharmaceuticals for Children Act, for PULMICORT/RHINOCORT (budesonide), CLARINEX (desloratadine), CUTIVATE/FLONASE/FLOVENT (fluticasone), OCULFOX (ofloxacin), FLUDARA (fludarabine), and FOSAMAX (alendronate).

The background material will become available no later than the day before the meeting and will be posted under the Pediatric Advisory Committee (PAC) docket Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm.* (Click on the year 2004 and scroll down to PAC meetings.)

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 1, 2004. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 1, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jan N. Johannessen at least 7 days in advance of the meeting.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 29, 2004

July 29, 2004.

William Hubbard

William K. Hubbard,
Associate Commissoner for Policy and Planning.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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